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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,489	FREEHAUF, KEITH	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7-25-06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-23 are presented and represent all of the claims under consideration.

The instant specification claims the benefit of prior-filed U.S. Provisional Application No. 60/530939, filed December 19, 2003. Support for each concentration range of the recited ingredients, as well as the pH range recited in claim 13, was not found in the '939 application. As such, the earliest effective U.S. filing date of the instant application has been determined to be March 1, 2004.

An Information Disclosure Statement filed July 25, 2006 is further acknowledged and has been reviewed.

Claims 3, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The metes and bounds of the recitation "insect growth-regulating compound is one that mimics juvenile hormones" in claim 3 cannot be precisely determined. Applicant should recite those compounds contemplated.

The recitation "increasing the amount of the already existing stabilizer" in claim 17 lacks clarity. Said amount is indefinite. It is unclear if the amount of stabilizer recited in claim 19 refers to the original amount or the amount added to decrease the pH of the premix.

Clarification is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 7 and 9-19 of copending Application No. 11/107,048 in view of Chabala et al., U.S. Patent 4,199,569, and Sutherland et al., U.S. Patent 4,910,219. The claims of the co-pending application are drawn to compositions for oral administration comprising avermectins, such as ivermectin, doramectin, abamectin, moxidectin, selamectin, and milbemycins, with an antioxidant such as sodium metabisulfite, ascorbic acid, propyl gallate, butylated hydroxyanisole or butylated hydroxytoluene; a surfactant such as hydrogenated castor oil; and a pH stabilizer, such as citric acid. The open language of the present claims allows for the inclusion of any number of additional active or inactive ingredients. Chabala teaches feed premixes comprising avermectins and milbemycins utilize carriers such as corn meal, citrus meal, fermentation residues, ground oyster shells, wheat shorts, molasses solubles, corn cob meal, bean mill feed, soy grits, dried grains and crushed limestone. See column 8, lines 11-21. Further, Sutherland teaches

compositions for veterinary medicine comprising macrolides of formula II may be formulated to include the wax glyceryl monostearate. See column 5, line 16.

This is a provisional obviousness-type double patenting rejection.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention. The claims are directed to a premix for an animal feed that exhibits an extended shelf life, and methods thereto. The specification does not reasonably provide enablement for the compositions and methods within the full scope of the claimed methods.

To be enabling, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC

1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547, the court recited eight factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The invention is drawn to a combination composition intended to be used as a premix for an animal feed comprising a parasitically effective amount of at least one of the anthelmintics avermectin or milbemycin formulated with various pharmaceutically acceptable surfactants, waxes, antioxidants, carrier vehicles, stabilizers and, optionally,

at least one insect growth-regulating compounds along with methods for extending the shelf life of a premix for an animal feed.

The relative skill of those in the art is high, generally that of a veterinarian or Ph.D. with expertise in the area of animal feed formulation.

However, according to Maxfield et al., US. Patent 4,597,969, formulations comprising avermectins and milbemycins are known to be unstable and to undergo substantial decomposition due to heat and moisture sensitivity. See the Abstract. Thus the prior art recognizes that the self-life of food supplements comprising avermectins and milbemycins are unpredictable and difficult to maintain.

Although the instant claims recite numerous pharmaceutically acceptable surfactants, waxes, antioxidants, carrier vehicles, stabilizers and, optionally, at least one insect growth-regulating compounds, the instant specification provides Assays for a single formulation that comprises invermectin without an insect growth-regulating compound. See Example 1 on page 15. In particular, the disclosure is clearly not predictable for formulations comprising milbemycins, optionally with an insect growth-regulating compound, or a stabilizer other than anhydrous citric acid. The skilled artisan would not reasonably expect that any or all of the claimed components in a premix feed would result in a stabilization preparation having a shelf-life that is extended.

The breadth of the claims

The claims are extremely broad and inclusive of any of the anthelmintics avermectin or milbemycin, formulated with numerous pharmaceutically acceptable

surfactants, waxes, antioxidants, carrier vehicles, stabilizers and, optionally, at least one insect growth regulating compounds.

The amount of direction or guidance provided and the presence or absence of working examples

There is a single working example drawn to a comparison with and without citric acid (Table II on page 17) under defined storage conditions with respect to temperature and humidity over time (pages 18-20). No results are provided drawn specifically to other premix formulations wherein a milbemycin or a different stabilizer is employed.

The quantity of experimentation necessary

Applicant has failed to provide guidance as to other combinations that would reasonably be expected to demonstrate an extension of the shelf life of various avermectins and milbemycins. In view of the industrial problem that is recognized in the prior art concerning stability of such formulations, the disclosure is not commensurate in scope with the present claims. No direction is provided to distinguish among the various stabilizers that appear to play the most significant role in stabilization of the final product. Absent reasonable *a priori* expectations of success for using any combinations of components to achieve an extended shelf-life of avermectins or milbemycins, one skilled in the art would have to test extensively the various pharmaceutically acceptable surfactants, waxes, antioxidants, carrier vehicles, stabilizers and, optionally, at least one insect growth-regulating compounds to discover which particular combination in a premix for an animal feed exhibits an extended shelf-life. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be

empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Due to the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that any combination of ingredients could be employed. Accordingly, the instant claims do not comply with the enablement requirements of 35 U.S.C. 112, first paragraph, since to practice the claimed invention would require a person of ordinary skill in the art to engage in undue experimentation with no assurance of success.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuvry et al., U.S. Patent 5,824,653, in view of Katoh et al., U.S. Patent 4,939,166, Chabala et al., U.S. Patent 4,199,569, Sutherland et al., U.S. Patent 4,910,219, Freehauf et al., U.S. Patent 7,001,889, and Carson et al., U.S. Patent 6,548,478.

Beuvry teaches anthelmintic compositions comprising avermectins, milbemycins, or derivatives thereof comprising surfactants and stabilizers. See column 2, line 37. As required by instant claim 2, ivermectin, a semisynthetic derivative of avermectins is disclosed in column 2, line 39. Another avermectin, abamectin, is part of the

formulation of Example 1, column 3. Further, the antioxidant, sodium metabisulfite, is encompassed in Example 1. The open language of the present claims allows for the inclusion of any number of additional active or inactive agents.

With respect to the requirements of the present claims for pharmaceutically acceptable surfactants, waxes, antioxidants, carrier vehicles and, optionally, insect growth-regulating compounds in animal feed compositions comprising avermectins and milbemycins:

Chabala teaches feed premixes comprising avermectins and milbemycins utilize carriers such as corn meal, citrus meal, fermentation residues, ground oyster shells, wheat shorts, molasses solubles, corn cob meal, bean mill feed, soy grits, dried grains and crushed limestone. See column 8, lines 11-21. Further, Sutherland teaches compositions for veterinary medicine comprising macrolides of formula II may be formulated to include the waxes glyceryl monostearate or coconut oil. See column 5, line 16. Katoh broadly teaches the inclusion of surfactants in a premix for an animal feed comprising macrolide compounds that are structurally analogous to avermectins and milbemycins. See column 10, lines 40-43, and column 14, lines 5-8. Carson teaches the inclusion of anhydrous citric acid in foodstuffs such as feed grain comprising macrolide antibiotics. See the Examples. As required by instant claim 13, the amount should be sufficient to provide a pH of from about 3.0 to about 7.0 in order to minimize the breakdown of the components of the mixture. See column 1, lines 51-61, and column 2. Freehauf teaches the inclusion of avermectins and milbemycins in oral compositions intended for swine or equine administration, wherein pH stabilizers

such as maleic acid or citric acid, antioxidants, such as sodium metabisulfite or ascorbic acid, and surfactants, such as hydrogenated castor oil, are further included.

The prior art does not teach optimal dosages and preferred shelf-life extensions that are herein claimed. However, concerning these parameters in the instant compositions and methods of use, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The determination of the optimum dosage range to employ with the presently claimed active and auxiliary agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as temperature, relative humidity, and pharmacological considerations, such as the pharmacokinetics and toxicology profiles of the particular compounds employed. Thus, in the absence of evidence to the contrary, the currently claimed specific ranges and shelf-life extensions are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In view of the combined teachings of the prior art, one skilled in the veterinary art would have been motivated to prepare a premix for an animal feed comprising at least one avermectin or milbemycin in combination with a pharmaceutically acceptable surfactant, wax, antioxidant, stabilizer and carrier vehicle with a reasonable expectation

of having an extended shelf-life. Such would have been obvious in the absence of evidence to the contrary because Carson teaches the inclusion of anhydrous citric acid in foodstuffs, such as feed grain comprising macrolide antibiotics, in amounts sufficient to provide a pH of from about 3.0 to about 7.0. The inclusion of anhydrous citric acid in animal feed will minimize the breakdown of the components of the mixture and extend the shelf life of the product.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached on 591-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

June 21, 2007